A SAFE AND HEALTHY ENVIRONMENT FOR CHILDREN

A National Longitudinal Cohort Study of Environmental Impacts on Children and Families

June 2000

The President's Task Force on Environmental Health Risks and Safety Risks to Children

THE PRESIDENT'S TASK FORCE ON ENVIRONMENTAL HEALTH RISKS AND SAFETY RISKS TO CHILDREN

President William Jefferson Clinton issued Executive Order 13045 on April 21, 1997, directing each Federal Agency to make it a high priority to identify, assess, and address children's environmental health and safety risks. In issuing this order, the President also created the Task Force on Environmental Health Risks and Safety Risks to Children, co-chaired by Donna E. Shalala, Secretary of the U.S. Department of Health and Human Services, and Carol M. Browner, Administrator of the U.S. Environmental Protection Agency. The Task Force was charged with recommending strategies for protecting children's environmental health and safety.

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THE LONGITUDINAL COHORT PLANNING GROUP

The Longitudinal Cohort Planning Group was organized under the auspices of the Developmental Disorders Workgroup of the President's Task Force on Environmental Health

Risks and Safety Risks to Children**.**

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EXECUTIVE SUMMARY

Executive Order 13045 (April 21, 1997) directs Federal agencies to make it a high priority to identify, assess, and address children's environmental health and safety risks, and created **the Task Force on Environmental Health Risks and Safety Risks to Children**. Co-chaired by the Secretary, HHS, and Administrator, EPA, the Task Force was charged to recommend strategies to protecting children's environmental health and safety, and chose four priorities: (1) asthma; (2) unintentional injuries; (3) cancer; and (4) developmental disorders. The Developmental Disorders (DD) Workgroup recognized that a large, prospective cohort study of children could offer a comprehensive approach to understanding how the environment, family, and society interact with the genetic constitution of the developing fetus and child. Large longitudinal studies of U.S. children were conducted 40-50 years ago, but the feasibility of conducting a modern-day longitudinal cohort study of children was in question.

On **January 12, 2000**, the Planning Committee of the DD Workgroup convened an expert panel to present state-of-the-art exposure assessment techniques and alternative study structures and methods to about 90 invited participants from government, academia, and private sector. Presentations highlighted issues to be considered in deciding the feasibility of such a study. General conclusions of participants' discussion were:

- General support and extremely positive encouragement for conducting a large cohort study.
- Realization that children cannot be studied apart from their parents and their families and that studies should be sensitive to behavioral, social, and cultural aspects of the children and families.
- Need to develop specific hypotheses using a longitudinal cohort approach.
- Critical need for broad-based support within the communities proposed to be studied.
- Need to address from the beginning ethical issues regarding collection, storage, and eventual distribution of information, biologic specimens, genetic material, and environmental samples.
- Observation that the study should take advantage of the latest in information technology.
- Need for resolution of issues of internal versus external validity, particularly regarding follow-up.
- Need for diversity of the study population; need for a "representative" sample was not resolved.
- Modern bio-analytic and environmental monitoring techniques should be planned into the study.
- Need for interaction/collaboration among all the Federal agencies.
- Need for new money to conduct the study.
- Need for a strong, central, small directing group dedicated solely to designing/conducting the study.

On January 13, the Planning Committee developed the following recommendations to the Task Force:
(1) The Task Force should plan a national longitudinal cohort study of children's environmental health.
(2) New money for this study is imperative.
(3) Full-time personnel are required to organize/oversee movement into the pre-pilot study planning phase.

TIMELINE FOR FUTURE ACTIONS: Pre-pilot Phase

April 2000	Develop study hypotheses that can only address important public health issues through longitudinal cohort study.
April 2000	Establish an interagency coordinating team to oversee/organize the pre-pilot planning.
May 2000	Begin to determine options for study design through consultations and

committees.

Jan-April 2000	Develop a proposed study design.
July-Sept 2001	Funding of first pilot studies.

INTRODUCTION

Evaluating the link between environmental exposures and developmental disorders in children is a difficult research challenge. The range of developmental disorders is extremely wide, as is the range of exposures that might effect a child's intellectual, physical, emotional or social growth and development. Many exposures have different effects when they occur at different times, either before or after birth; for some exposures this critical window may be short. Short critical windows make the retrospective study of exposures that might cause developmental disorders in children very difficult. A prospective, longitudinal study of pre- and post- natal growth and development, in which information is collected at multiple points in time about pregnant women and subsequently about their children and families, is the optimum design with which to study the dynamic nature of growth and development. However, longitudinal cohort studies of pregnancy and childhood are difficult to carry out. The last such large cohort studies in the United States were begun in the 1950s and early 1960s, and the feasibility of conducting such a study in present times is uncertain.

To explore the feasibility of conducting a large, longitudinal cohort of pregnancy, childhood and adolescence, the Centers for Disease Control and Prevention, U.S. Environmental Protection Agency and National Institutes of Health, under the auspices of the President's Task Force on Environmental Health Risks and Safety Risks fo Children, conducted a consultation on January 12 and 13, 2000. Experts from within and outside the Government who have experience in the design and conduct of large, longitudinal cohort studies were invited to provide advice regarding the feasibility of conducting a longitudinal cohort study, as well as regarding issues that must be considered is such an undertaking. This report details the background of this consultation, as well as its results.

A SAFE AND HEALTHY ENVIRONMENT FOR CHILDREN

A growing body of science indicates that a child's growth and development are enhanced by a healthy and safe environment. Conversely, children may suffer disproportionately from environmental health and safety risks. Some normal childhood behaviors may result in exposures to physical, chemical, biological, or psychosocial threats, contaminants, and safety hazards. Pound for pound, children eat and drink more food and liquids, and breathe more air than adults. Children grow rapidly, and their absorption, distribution, metabolism, and excretion of various substances change over time, affecting how well they tolerate environmental exposures. Children by their very nature - small in size and weight - are less able to withstand the energy forces associated with injury and are less well protected by adult/standard safety features.

A child's environment represents more than hazards related to a specific exposure. It characterizes the totality of conditions and milieu in which a child grows and develops. The consequences of an unsafe and unhealthy environment may have long latency periods that result in untoward outcomes later in time. Thus, the scope of securing a safe and healthy environment for children is broad and encompasses the tenets of protection, prevention, and promotion throughout the life cycle.

The President's Task Force on Environmental Health Risks and Safety Risks to Children is

guided by a directorate comprised of a senior staff planning committee and workgroups on (1) program implementation and (2) data needs and research. In addition, four workgroups were formed to address the following priority areas: (1) asthma, (2) unintentional injuries, (3) cancer, and (4) developmental disorders.

Collectively, these priority areas represent key sentinel conditions concerning childhood morbidity and mortality. They also represent important opportunities for disease prevention and health promotion to prevent or relieve lifelong injury, illness and disability. In addition, their successful resolution requires broad cooperation and support from quality health and human services, environmental and legal protection, quality education, nutritious and safe foods, and safe and clean transportation. A safe and healthy environment for children requires safe labor and industry practices, safe and appropriate housing, safe consumer products and energy, as well as sound complementary fiscal, economic, domestic, and science policy.

The President's Task Force on Environmental Health Risks and Safety Risks to Children has employed four principles in directing its efforts: (1) primary prevention - eliminating the threat of exposure to harmful events or hazardous substances; (2) secondary prevention - providing screening, treatment, and follow-up care before the condition deteriorates to irreversible morbidity or mortality; (3) surveillance and monitoring - providing data for evaluation, decision making and resource allocations; and (4) research - generating new knowledge for effective primary prevention and quality treatment.

STRATEGIC SCIENCE

Evaluating the link in humans between environmental exposures and developmental disorders is a major research challenge given the range of outcomes that may arise from one exposure and the variety of factors that can result in a given outcome. The range of developmental disorders affecting children is wide and includes intrauterine growth retardation, infant mortality, birth defects, suboptimal postnatal growth and development, functional deficits (e.g., neurobehavioral, immune, reproductive, respiratory) and possibly the foundations for chronic diseases of adulthood. The factors that might be responsible for these outcomes are equally diverse. Prenatally, they range from genetic disorders to *in utero* exposures to infectious agents, poor maternal nutrition, tobacco, alcohol, drugs, and other chemicals. Even before conception, exposures of parents to radiation and chemotherapeutic agents have been linked with developmental disorders. In early childhood, exposures of concern run the gamut from lead and environmental tobacco smoke to lack of a nurturing and stimulating environment. The timing and pattern of these exposures impacts the types of effects that are seen, and the degree to which children are affected.

It is estimated that more than 150,000 babies in the U.S. (about 4 percent of all live births) are born with significant birth defects each year. Ranging from severe to mild, 2% to 17% of children in the U.S. have a developmental disorder, such as cerebral palsy, mental retardation, autism, or a hearing impairment. While the exact proportion attributable to environmental factors is unknown, exposure to environmental hazards often have lasting and profound consequences for children's growth and development that may not manifest themselves until adulthood. A child's nervous system, reproductive organs, and immune system grow and develop rapidly during the first months and years of life. As organ structures develop, vital

connections between cells are established. These delicate developmental processes in children may be easily and irreversibly disrupted by environmental substances, such as lead, mercury, and polychlorinated biphenyls (PCBs), producing lasting changes in intelligence, behavior, and reproductive capability.

The consequences of both prenatal and postnatal lead exposure demonstrate the importance of investigating both acute and life-long toxicity and harmful effects in several domains. Lead is a neurotoxic metal that affects areas of the brain associated with regulating behavior by altering the output of neurotransmitters and disrupting the development of nerve cells. Exposure of pregnant women to lead may result in transfer of the metal to a developing fetus, resulting in developmental problems, while exposure of children, even to low levels, can cause lowered intelligence, reading and learning disabilities, impaired hearing, reduced attention span, hyperactivity, and antisocial behavior. Many of these problems last a lifetime and impact the quality of life of the child and his or her family.

Consequently, the President's Task Force on Environmental Health Risks and Safety Risks to Children seeks to establish and coordinate efforts of a unique multi-agency strategy to implement a longitudinal cohort study of environmental impacts on children and families. This national effort will assess the effects of early and ongoing exposures to physical, chemical, biological and psycho-social environmental influences on children's well-being, identifying both risk and protective factors.

SCOPE AND NATURE OF THE INVESTIGATION

In principle, the study design that can best define the effects of multiple environmental exposures, occurring at multiple points during development, on a wide array of possible outcomes is the prospective cohort study. A prospective cohort study can evaluate both chronic and intermittent exposures while avoiding many of the difficulties that alternative study designs have when attempting to reconstruct this information. However, few cohort studies of children have actually been carried out. The only U.S. studies to take a longitudinal approach to examining multiple facets of exposures and specific health outcomes in children were the Federally sponsored Collaborative Perinatal Project, Child Health and Development Studies, and Kauai Child Development Study, all of which were done about 40 years ago. In other countries, such studies are currently underway (e.g. the Avon Longitudinal Study of Pregnancy, Adolescence and Childhood; and the Danish National Birth Cohort Study) or are being planned (e.g. a study of Norwegian children). A similar cohort approach has been used to study chronic health conditions in adults, e.g., the Framingham study.

U.S. researchers have considered conducting a similar present-day study of children, but no planning for such an effort has been undertaken to date due to the expense and time required to plan and conduct a longitudinal study. However, given the recent developments in biomarkers of exposures and outcomes and the experience gained in cohort studies with a narrow scope, it is desirable to now consider conducting a large, prospective cohort study of children, their parents and their families. This would represent a more comprehensive approach to understanding how the environment, family and society interact with the genetic constitution of the developing fetus and child to foster optimal childhood growth and development, and how environmental exposures can adversely affect that growth and development.

Understanding the complexity of human growth and development requires special investigative approaches. Conducting a longitudinal cohort study of children and families is such a special vehicle and it is a unique and necessary approach to assess the effects of prenatal, postnatal, and early childhood exposures to physical, chemical, biological, and psycho-social environmental influences on children's well-being. Central to understanding children's growth and development are the biological, behavioral, social, emotional, educational, and contextual consequences for identifying both risk and protective factors.

The longitudinal study represents a major legacy effort inaugurated by the Task Force. This effort will create an extensive national scientific resource and an interactive and collaborative research infrastructure for basic and applied scientists that will accelerate the pace of gaining new knowledge to improve the health and well-being of children for successive generations. It will enable maximum advantage of new developments in measurement, instrumentation and specimen preservation in the discovery of new knowledge integrated with information garnered from the genome project. This new investment will complement the existing children's environmental health research centers supported by this nation. Funding this research will represent a major commitment to discovering basic mechanisms of developmental disorders and environmental factors that influence growth and developmental processes.

The expertise of several agencies has been combined to explore the possibilities for developing a longitudinal cohort study of children. The study will begin during pregnancy and is intended to follow the children into adulthood. Assessments and data collection will include adverse physical, functional, and psycho-social consequences of environmental exposures. During FY1999 and FY2000, experts were consulted to assess the feasibility and benefits from various designs of longitudinal studies to guide future development of planning a study, conducting pilot tests, and providing information, including cost projections and scope, on which to base design decisions.

ASSESSING FEASIBILITY

On January 12, 2000, a group of experts with experience in conducting large cohort studies was convened in Washington, D.C. by the Planning Group. Two presentations were made as background to the discussions, one on exposure measurements by Dr. Maurice Berry (EPA/ORD/NERL), and one on biological specimen collection, analysis and storage by Dr. Terry Phillips (NIH/OD). Subsequently, experts on various types of cohort studies presented background on their respective approaches. These included a review of 1) the National Collaborative Perinatal Project by Dr. Karin Nelson (NIH/NINDS); 2) the Danish national cohort study by Dr. Jorn Olsen (Danish Epidemiology Science Center); 3) the Bogalusa Heart Study by Dr. Gerald Berenson (Tulane University); 4) the Avon Longitudinal Study of Pregnancy and Childhood by Dr. Jean Golding (University of Bristol); 5) HMO-based studies by Dr. Barbara Cohn (The Public Health Institute, Berkeley) and Dr. Diana Petitti (Kaiser Permanente, Southern California); and 6) the Nurses Health Study by Dr. Frank Speizer (Harvard University). Presentations highlighted issues that need to be considered in deciding to commence such a study, including specific advantages and disadvantages of each study type, and its overall feasibility. The experts were asked to provide information regarding the value and feasibility of a large, longitudinal study of children and the environment. Invited discussants

commented on each approach and general discussion of all of the approaches was held at the end of the day. The following points and suggestions were made:

- While the specific nature of the longitudinal cohort study will require time and careful consideration of nominal hypotheses, there was general support and extremely positive sentiment for the possibility of conducting a large cohort study.

- Since children cannot be separated from the families in which they live, a longitudinal study must be a study of children, parents and families, and not just a study of children. The study should both collect information on and be sensitive to the behavioral, social and cultural aspects of the children and their families.

- Before giving further consideration to the settings and structure for the study, hypotheses must be developed. There was agreement that a large, long-term longitudinal study must address questions that are of importance to public health and the health of children, and that would be difficult or impossible to address with a smaller, shorter-term and less expensive design. A benefit of a longitudinal design is the ability to evaluate biomarkers of exposures and environmental measurements during critical windows of development, which continue throughout the life course, and to link exposures at particular times in development with their effects.

  - ✓ There was considerable discussion, both from the experts and within the Planning Group, regarding how narrowly or broadly focused the hypothesis should be. However, it was recognized that a study intending to address the health, growth and development of children must collect a wide range of information, from direct assessments of the immediate environment to indirect factors that may relate to a child's ultimate growth and development. Wide-ranging data collection does not mean such a study is merely a "fishing expedition."

  - ✓ Rather than specifying a particular setting for the study, such as within an HMO, a University hospital clinic, a geographic region, etc., the consultants believed that it was preferable to specify the study design, the common protocol, etc., and let investigators representing different institutions and settings submit proposals describing how they would carry out the protocol.

  - ✓ One design feature to be considered is a "core protocol" that all participants would follow, with the opportunity to incorporate modular components or "special studies" based on the characteristics, interests and expertise of the individual sites.

- Building support for a large cohort study both within the technical communities and study participants will be critical. In particular, two similar cohort studies planned or underway in Europe were either severely delayed or required major modification due to failure to build support within the community of general practitioner physicians. The support for the study within the community of parents is as crucial as the support from the medical and research communities. Input from all of these communities (parent, medical and research) should be obtained early in the process.

  - ✓ Ethical issues regarding collection, storage and eventual distribution of information, biologic specimens, genetic material, and environmental samples are paramount and must be addressed from the beginning of the planning process.

  - ✓ The need to garner support for the study should not be allowed to determine the type of information collected. In particular, simply allowing interested parties to exchange their support for questions or topics to be included will result in a poorly designed and unfocused study.

- Consideration should be given to the external and internal validity of the study, particularly with respect to

longitudinal follow-up. Individuals who can be identified before conception, who present early for antenatal care, who can be followed successfully over time, or who have exposures of particular interest, are probably not representative of the general population. During the planning phase, the potentially conflicting issues of "representativeness" versus the requirements to carry out long-term follow up successfully and to address hypotheses of particular interest must be resolved. The consultants themselves could not agree whether the study population should be chosen to be representative of a given area or whether it should be selected to be diverse in its composition and in environmental exposures, but not necessarily representative. All agreed that regardless of this conflict, diversity of the study population was important.

- The study should take advantage of the latest in information technology, particularly the Internet. Modern information technology should be incorporated into the design and conduct of the study from the beginning of planning, rather than being added after the study has already been designed.

- Similarly, modern bio-analytic and environmental monitoring techniques should be incorporated into the study during the planning phase. Some of these techniques already exist, but many may need to be developed specifically for this study. Banking samples for future use as technology evolves was discussed; its successful implementation will require resolution of many issues, particularly in logistics and ethics.

- Provisions and policies for public use of the collected information-- the data on the study forms, the biological specimens, and the environmental samples -- should be incorporated during the design phase, rather than added later. In this context, "public" is defined as both the research community and the general public. However, concerns were raised about the misunderstandings that can occur when individuals unfamiliar with a complex study are allowed to try to analyze the collected data without appropriate guidance and assistance.

- Long-term maintenance and ownership of both the study data and particularly the biological and environmental specimens should be addressed during the planning of the study. Provision should be made to assure adequate funds and facilities to store the biological specimens after the designers and investigators of the study have retired. The plan should be sensitive to the wishes of the study subjects, even years after the data and specimens have been collected.

- Several organizational issues were raised:

✓ Opportunities for public-private (foundations, industry, etc) partnerships should be explored.

✓ Interactions among the Federal Agencies involved will be crucial to the success of this project. More than one presenter expressed concern that conflicts among Agencies for control of the study might doom the entire project.

✓ The presenters, discussants and Planning Group all believed that "new money" must be allocated for a large, longitudinal cohort study to proceed. If Agencies were required to fund this large and expensive cohort from existing allocations, the accompanying reduction in funds available for both Extramural and Intramural research is likely to erode the support of both the Federal and University research communities. Erosion of this critical support would be a serious threat to any planned study.

✓ A strong, central and probably small directing group, dedicated solely to the design and conduct of the study, will be necessary to avoid the pitfalls raised during the consultation.

- Since a large, longitudinal study of parents and children, beginning prenatally and continuing through childhood has not been done in the United States since the 1960s, the designers of the proposed study were encouraged to think boldly. This study should be a trail-blazer in the areas of ethics, data collection,

information technology, biological analytic techniques and other areas.

RECOMMENDATIONS AND NEXT STEPS

The Longitudinal Cohort Study Planning Group met on January 13, 2000, to review the discussions at the consultation and to draft recommendations to the Task Force. The following general recommendations are made:

- **Based on the consultation and discussions in the Planning Group, the Task Force should move ahead with the planning of a national longitudinal cohort study on children's environmental health.**

- **To conduct a study of such magnitude and importance will require new money that does not reduce current research funds of the various agencies involved**. The Planning Group is in complete agreement with the expert consultants on this point. If current research funds are reduced in order to carry out this study, the general research community would be adversely affected and would not be willing to support the study and its goals.

- **Full-time personnel are required to organize and oversee the numerous activities that will be required to move into the pre-pilot planning phase of the process**. In order to set up the various activities necessary to keep the process moving and to prepare for launching a national cohort study within the next 5 years, an **Interagency Coordinating Team** of a small number (2-3) of full-time individuals must be assigned to this effort. This could be accomplished, for example, by detailing an individual from agencies involved in the activities (e.g., EPA, NIH, and CDC) to a central location in the Washington, DC, area for coordinating these activities. This group would be advised by the Interagency Planning Group, and would be responsible to the Executive Secretariat of the Task Force, as well as their own agencies.

  The team would be responsible for the day-to-day management of all aspects of the pre-pilot phase. This would include planning the various additional consultations and committees (described below); compiling an inventory of other already planned studies that are related to the longitudinal cohort study, including instruments/techniques that are already being developed; setting up meetings/conference calls of the larger Planning Group when needed; writing RFPs or other documents for soliciting proposals for funding of the pre-pilot efforts; communicating with the Task Force, and other appropriate entities on a regular basis; and PR functions such as answering inquiries about the study and producing materials that can be distributed to appropriate interested parties, e.g., government agencies that have not been a part of the planning process to date, academic institutions, parent groups. Maintaining the "spirit" of interagency collaboration at all levels was cited as being extremely important. It is hoped that this proposed structure for coordinating the planning process can be in place in the **next 3 months.**

Included with this concept of the study and recommendations to move forward with planning and the pre-pilot phase is a work plan and a timeline that clearly define the next steps necessary.

WORKPLAN AND TIMELINE FOR THE PRE-PILOT PHASE

April, 2000 ***Develop hypotheses for the study that address important public health issues that can only or best be addressed in this study***. Many of the other

activities to be conducted in the planning and pre-pilot phase hinge on the statement of the hypotheses to be tested in the study. Work has already begun on this effort within the Planning Group.

April, 2000 ***Set up an interagency coordinating team to oversee and organize activities during the pre-pilot planning phase.*** Detail individuals from at least the major agencies involved in planning, e.g., EPA, NIH, and CDC, to a central location in the Washington, DC, area for coordinating these activities.

Beginning May, 2000 ***Determine options for study design and conduct through committee/consultation work. Activities would include:***

- organizing additional consultations on ethics and legal issues, social and cultural issues, community involvement/partnerships (public/private/philanthropic), communication, and information technology;
- setting up committees to discuss options for study design, follow-up mechanisms, exposure measurements, outcome measurements, biological specimen collection, analysis, and storage, ownership and maintenance of data and samples; and
- developing a structure that includes the appropriate advisory committees (e.g., ethics, scientific, and other advisory groups as appropriate).

Jan-April 2001 ***Develop a proposed study design.*** After a series of consultations, as described above, a proposed study design would be developed by the Planning Group and Coordinating Team based on information gained from the consultations and committee work.

July-Sept 2001 ***Funding of first pilot studies.*** The number and nature of these first pilot studies will be determined by the information gathered through the workshops/consultations, and other methods development that has been identified by the Planning Group.

CONCLUSION

As scientific and technological advances are made, the environment will undoubtedly change. More chemicals and pesticides designed to add comfort and productivity will be introduced. New emissions will alter air quality. High tech innovations will likely add to the number of known and unknown hazards. The interaction between these environmental influences and the biological and psycho-social environment of the child is not known. However, the risk to our planet, particularly our children, likely will rise each year. Consequently, the need for new knowledge to promote well-being and to protect and prevent untoward outcomes similarly rises. Fundamental research, surveillance, and program evaluation on such critical topics as the relationship between the environment and the effect it has on children's health arises from many

scientific disciplines and is supported through several mechanisms. The special nature of children, with their dynamic developmental trajectory, requires a longitudinal approach to assure maximum scientific information on and understanding of adverse health and safety risks in children resulting from exposure to a broad range of environmental agents. Such an enterprise is not only feasible but essential.

The President's Task Force on Environmental Health Risks and Safety Risks to Children has been successful in coordinating multi-disciplinary efforts and the skills of multiple governmental agencies to achieve one common goal – making the future for our children brighter, healthier, and safer. The implementation and execution of a national longitudinal cohort study of children and their families will generate new knowledge critical for new and innovative interventions to bridge the gulfs between different scientific disciplines and assure a safe and healthy environment for children in the coming millennium.